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III. Summary of Safety and Effectiveness

A. Applicant

Name: MedCom GmbH
Address: 12 Rundeturmstrasse
Darmstadt, HE 64283
Germany

B. Device

Trade name:	Exomio Model 2.0 SP1
Classification name:	Radiation Therapy Simulation System
Classification:	Class II §892.5840
Product code:	KPQ

C. Device Trade Name

Exomio

D. Predicate device

Device trade name: Exomio, Model 1.1
510(k) number: K022219
Company name: MedCom GmbH

E. Description

Exomio is a programmable (Software) medical device aiming to fully provide the physicians with necessary visualisation and image manipulation tools to prepare the patient's RT simulation virtually in absence of the physical patient and the physical simulator. This is done using the patient's CT data set, including the attached on the patient's skin registration markers, instead of the physical patient. This process it called virtual simulation and Exomio, as well as other similar systems, is called CT-based or Virtual Radiation Treatment Simulation System.

Exomio provides tools to support clinician's decision making through the use of enhanced visualization of the patient data set and treatment parameters. 3-D visualization provides an excellent overview of the patient's anatomy. In addition, the relation between treatment beams and tumor can be investigated in detail using Exomio's navigation tools. All this unique functionality is provided to the clinics with aim the overall improvement of the RT simulation process.

Exomio is able, using the DICOM standard, to export all parameters necessary for the treatment of the patient as well as the images to other devices supporting DICOM RT Plan and Structure Set. This way the whole procedure becomes a lot faster saving even more time for the physician and the rest medical staff.

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F. Intended Use

The Exomio Radiation Treatment Simulation System is used for CT-based diagnostic image analysis, while also providing treatment planning tools to the physician, such as: contouring and segmentation (manual or automatic), radiation treatment field editing and 3D visualization of the virtual treatment setup. Moreover, it includes useful treatment setup export capabilities to enable the communication with compatible medical devices.

G. Summary of Technical Considerations

Exomio 2.0 SP 1 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2003

Mr. Stefan Walter
Quality Manager
MedCom GmbH
12 Rundeturmstrasse
Darmstadt, HE64283
GERMANY

Re: K032550
Trade/Device Name: Exomio Model 2.0 SP1
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: 90 KPQ
Dated: August 13, 2003
Received: August 26, 2003

Dear Mr. Walter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VIII. Indications for Use Statement

510(k) Number (if known): Not Available K032550

Device Name: Exomio 2.0 SP 1

Indications for Use: The Exomio Radiation Treatment Simulation System is used for CT-based diagnostic image analysis, while also providing treatment planning tools to the physician, such as: contouring and segmentation (manual or automatic), radiation treatment field editing and 3D visualization of the virtual treatment setup. Moreover, it includes useful treatment setup export capabilities to enable the communication with compatible medical devices.

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032550

Prescription Use ✓
(Per 21 CFR 801.109)